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In the Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

vs.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants.

On Appeal from the Court of Appeal of the State of California First Appellate District

MOTION TO DISMISS OR AFFIRM

RICHARD M. PEARL
California Rural Legal Assistance
115 Sansome Street, Room 900
San Francisco, California 94104
Telephone: (415) 421-3405

JAMES RUMBLE
Attorney at Law
700 Spring Street
Santa Cruz, California 95060
Telephone: (408) 423-4321

Attorneys for Appellees George Kievlan, et al.

BOWNE-PERNAU WALSH • 1045 SANSOME ST. • S.F., CA 94111 • (415) 981-7882

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On Appeal from the Court of Appeal
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MOTION TO DISMISS OR AFFIRM

Appellees respectfully move to dismiss the appeal filed herein, or in the alternative to affirm the judgment of the Court of Appeal of the State of California, First Appellate District. Rule 16(b) and (d).

(a) THE NATURE OF THE PROCEEDINGS

This lawsuit was brought by six elderly persons against one of the nation's largest manufacturers of hearing aids, Dahlberg Electronics, Inc., its parent company, Detection

Sciences, Inc. and a local hearing aid dealer who sold Dahlberg hearing aids.[1]

In addition to individual claims for rescission and damages based on fraud and misrepresentation by the local dealer, plaintiffs sought an injunction against Dahlberg's hearing aid advertisements. These advertisements proclaimed that Dahlberg hearing aids would benefit persons with hearing loss caused by nerve deafness or nerve impairment and requested interested persons to write to Dahlberg for more information.[2] Plaintiffs alleged that such advertisements violated California Health and Safety Code section 26463(m), which prohibits advertising of medical devices represented to have any effect on "diseases or disorders of the ear and auditory apparatus, including hearing loss and deafness". The injunction was sought on behalf of the general public pursuant to California Civil Code section 3369.[3]

Plaintiffs' claims against the local hearing aid dealer were settled prior to trial. The individual plaintiffs' purchases of unneeded hearings aids were rescinded, and in addition, five of the plaintiffs received punitive damages of seven hundred dollars ($700.00) each.

On plaintiffs' injunction claim, the superior court ruled that Dahlberg had violated section 26463(m), and that although it could continue to advertise "its place of business, that Dahlberg hearing aids are sold there, the prices of the instruments or any other information of that nature", it would be enjoined from representing that its hearing aids "have any effect on diseases or disorders of the ear, including hearing loss and deafness".

[1]For convenience, appellants Dahlberg Electronics, Inc. and Detection Sciences, Inc. will be collectively referred to as "Appellant" or "Dahlberg" in this Brief.

[2]Copies of the advertisements in question are appended hereto as Exhibit 1.

[3]California Civil Code Section 3369 read, in relevant part:

". . .

2. Any person performing or proposing to perform an act of unfair competition within this State may be enjoined in any court of competent jurisdiction.

. . .

5. Actions for injunction under this section may be prosecuted by the Attorney General or any district attorney in this State in the name of the people of the State of California upon their own complaint or upon the complaint of any board, officer, person, corporation or association or by any person acting for the interests of itself, its members or the general public."

(b) STATUTES INVOLVED.

This appeal involves California Health and Safety Code section 26463, which is part of California's Sherman Food, Drug, and Cosmetic law (California Health & Saf. Code, div. 21). Section 26463 is part of the chapter of the Sherman Act dealing with "Advertising" (Ch. 4, art. 3); it reads:

> "It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:
>
> (a) Appendicitis.
> (b) Blood disorders.
> (c) Bone or joint diseases.
> (d) Kidney disease or disorders.
> (e) Cancer.
> (f) Carbuncles.
> (g) Disease, disorder or condition of the eye.
> (h) Diabetes.
> (i) Diphtheria.

(j) Gall bladder disease or disorder.

(k) Heart and vascular diseases.

(l) High blood pressure.

(m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness.

(n) Measles.

(o) Meningitis.

(p) Mental disease or mental retardation.

(q) Paralysis.

(r) Pneumonia.

(s) Poliomyelitis.

(t) Prostate gland disorders.

(u) Conditions of the scalp, affecting hair loss, or baldness.

(v) Alcoholism.

(w) Peridontal diseases.

(x) Epilepsy.

(y) Goiter.

(z) Endocrine disorders.

(aa) Sexual impotence.

(ab) Sinus infection.

(ac) Encephalitis.

(ad) Tumors.

(ae) Venereal disease.

(af) Tuberculosis.

(ag) Ulcers of the stomach.

(ah) Varicose ulcers.

(ai) Scarlet fever.

(aj) Typhoid fever.

(ak) Whooping cough."

Two other sections relevant here are California Health and Safety Code sections 26464 and 26465. Section 26464 states:

> "An advertisement which is not unlawful under Section 26460 is not unlawful under Section 26463 if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices."

Section 26465 reads:

> "Whenever the [California Department of Health] determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health."

(c) QUESTIONS PRESENTED.

I. Whether the court below was correct in holding that California Health and Safety Code section 26463(m) has not been preempted by the F.D.A. hearing aid regulations promulgated pursuant to the Medical Device Amendments of 1976?

II. Whether the court below was correct in holding that Health and Safety Code section 26463(m) and the injunction issued pursuant to it do not infringe upon appellant's constitutional right to free speech?

(d) STATEMENT OF THE CASE.

On August 13, 1975, the Superior Court of Santa Cruz County, Judge Harry F. Brauer, heard Plaintiffs' Motion for Summary Judgment, in which Plaintiffs sought an injunction barring Dahlberg from continuing to advertise its hearing aids in violation of California Health and Safety Code section 26463(m). In support of their claim, plaintiffs presented the following facts about Dahlberg's advertisements to the superior court:

1. Copies of four advertisements used to promote Dahlberg hearing aids were submitted. (C.T. 200-203).[4] Two of the advertisements were those Dahlberg stated were the advertisements that it ran in several magazines of national circulation (C.T. 206) (Ex. 1, pp. 1-3); The other two ads were run by the local dealer. (Ex. 1, pp. 4-5).

2. The advertisements solicited responses from persons with hearing problems, and provided a form for them to fill out and mail to Dahlberg. These forms were then sent by Dahlberg to local Dahlberg dealers, who used these "leads" to sell hearing aids by making personal visits to the homes of the persons who had responded. (C.T. 208-212).

3. Dahlberg's advertisements produced 11,903 postcard responses from Californians during the period between January 1, 1972 and February 14, 1973. (C.T. 213).

The plaintiffs also presented facts demonstrating the harm caused by such advertisements. These included serious and repeated incidents of abusive sales practices used by

[4]See Exhibit 1.

the local Dahlberg dealer, resulting in the plaintiffs being sold expensive hearing aids which could not or did not help them, and which in several cases were not medically appropriate. (C.T. 32-91).

Evidence of a widespread pattern of similar abuses in the hearing aid industry generally was demonstrated by *A Report On Hearing Aid Health Care* (September, 1974), prepared by an inter-departmental task force created by the United States Department of Health, Education and Welfare to study hearing aid health care issues.[5] (C.T. 124-194). That report concluded that the medical problems of thousands of persons go undiagnosed because most persons with hearing problems go to a hearing aid dealer before they go to a physician or audiologist. The report also concluded that many persons are sold hearing aids who cannot be helped by them, and many others are sold the wrong type of hearing aid. The report also found that misleading advertising and high pressure sales were prevalent in the hearing aid industry, and that hearing aids were being sold at excessively high prices, especially to the elderly.

In its response (C.T. 235-275), the appellant did not dispute any of these facts and produced no counter-evidence on any of the factual issues, although it was its duty to do so under California law. California Code of Civil Procedure § 437c; California Evidence Code § 455; *see, Cornelison v. Kornbouth,* 15 Cal.3d 590, 595-596, 125 Cal.Rptr. 557 (1975).

[5]This report, as subsequently modified, formed the basis for the Food and Drug Administration's regulations on hearing aids, discussed in greater detail *infra* at pp. 12-30. 41 Fed.Reg. 16756 (April 21, 1976).

The appellant offered only two defenses to plaintiffs' motion:

1. That section 26463(m) was applicable only to advertisements claiming hearing aids would have a "curative or therapeutic" effect, and that Dahlberg's advertisements were not within its scope because they represented hearing aids would have a "compensatory" effect;

2. That bills amending Health and Safety Code section 26463(m) were before the California Legislature, and therefore the court should not decide the issue until that legislation had been passed or defeated.[6]

The appellant did *not* raise the argument that the statute violated its First Amendment right to freedom of speech.

Based on this evidence and the arguments presented by the parties, the trial court issued an opinion sustaining plaintiffs' claim. (Appellant's Jurisdictional Statement hereinafter "J.S.", Ex. B). It found, *inter alia,* that Dahlberg's hearing aid advertisements were both "extensive" and "effective".

1. "Dahlberg Electronics advertises its hearing aids extensively in national publications." (C.T. 301).

2. "Other advertisements are distributed by Dahlberg to its local dealers . . . ." (C.T. 302).

3. "These advertisements stress that Dahlberg's 'Miracle Ear' hearing aid is designed for those who suffer from nerve impairment or mild nerve deafness and that the device will allow the wearer to hear more clearly." (C.T. 302).

[6]Those bills subsequently were defeated.

4. "Dahlberg's advertising campaign has been effective." (C.T. 302).

5. "Between January 1, 1972 and February 14, 1973, 11,903 postcard responses [to Dahlberg's advertisements] were received by Dahlberg from California residents, who were then referred to local Dahlberg dealers." (C.T. 302).

The court also found that because of these advertisements, the plaintiffs and the public in general were being irreparably harmed:

6. "Defendant Dahlberg's advertisements have the tendency and capacity to injure many people who are hard of hearing and who read said advertisements." (C.T. 303).

7. "These people rely to their detriment on the defendant's representation that Dahlberg hearing aids will help them." (C.T. 303).

8. "The injuries they suffer include buying unnecessary hearing aids and foregoing necessary diagnosis and treatment." (C.T. 303).

The court examined these facts in light of the purposes of the statute:

> "That § 26463 should be given a broad construction is also apparent from the legislative policy underlying the Pure Drugs Act. Basically the purpose of that legislation was to (1) encourage the general public to seek professional care for the conditions listed; and (2) prevent the commercial exploitation of the general public by the advertising of drugs or devices which may be useful but whose efficacy in particular cases cannot be determined by laymen. § 26464, § 26465; *People v. Ryan,* 101 C.A.2d 927, 931 to 932 (1951)." (J.S. at 41).

It then found that these purposes were directly applicable to hearing aid advertisements:

> "Those policy considerations clearly apply to hearing aids, devices which help some persons suffering from impaired hearing and do not help others. As people with hearing defects desperately want help, they are especially suggestible. Finally, the devices are expensive; and they are needed primarily by the elderly, a class traditionally the objects of legislative solicitude and entitled to it." *(Ibid).*

It concluded by enjoining appellant's advertisements, in language that tracks the language of section 26463(m):

> "Defendants . . . are permanently enjoined and restrained from advertising their hearing aids in California by representing that said hearing aids have any effect on disease or disorders of the ear, or auditory apparatus, including hearing loss and deafness." (*Id.* at 44).

However, the court explicitly qualified the injunction by noting:

> "The use of the term hearing aid in and of itself is not a violation of Section 26463(m), and nothing contained herein preludes defendants or their dealers from advertising their place of business, that Dahlberg hearing aids are sold there, the prices of their hearing aids, or any other information of that nature." (*Id.* at 42).

On appeal to the California District Court of Appeal, the appellant contested the merits of the trial court's interpretation of Health and Safety Code section 26463(m). In addition, for the first time, it raised the issues of whether the statute violated the First Amendment and whether it had been preempted under federal law.

The decision of the court of appeal (J.S., Ex. A) affirmed the judgment of the trial court. First, the appellate court found that the appellant's attempt to construe the statute to exclude advertisements representing "compensatory" effects was contrary to the express language of the statute, and that the statute prohibited advertisements representing hearing aids to have "any effect" on hearing loss or deafness. (*Id.* at 30).

On the First Amendment issue, the court specifically declined to reach the merits of appellant's claim because it found that the advertisements were misleading, and therefore beyond the scope of any First Amendment protection; the court said:

> "It is clear from the copies of the advertisements that are included in the record that the advertisements were misleading in that they convey the impression that the hearing aid would have a curative or therapeutic effect." (*Id.* at 31-32).

Finally, on the preemption issue, the court found that the statute was not preempted by federal law because it did not impose a "requirement" relating to the safety and effectiveness of hearing aids, and because even if it was a requirement, it was not different from or in addition to any requirement under the federal regulations. (*Id.* at 32-34).[7]

Appellant's Petition for Hearing by the California Supreme Court was denied on June 15, 1978. (J.S., Ex. E).

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[7]At this point, it should be noted that the California Department of Health, the state agency responsible for enforcing section 26463, filed an *amicus curiae brief* on behalf of the plaintiffs in the court of appeal opposing both Dahlberg's statutory interpretation and preemption arguments.

(e) THE CASE PRESENTS NO SUBSTANTIAL FEDERAL QUESTION.

I. California Health And Safety Code Section 26463(m) Has Not Been Preempted By The F.D.A. Hearing Aid Regulations Promulgated Pursuant to The Medical Device Amendments Of 1976.

Appellant claims that the court below erred in rejecting its contentions that California Health and Safety code section 26463(m) was preempted by the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301, *et seq.*, as amended by the Medical Device Amendments of 1976, Pub.L. 94-295, 90 Stat. 539) and the hearing aid regulations promulgated under it by the Food and Drug Administration (hereinafter "F.D.A.") (21 C.F.R. §§ 801.420 and 801.421 (42 Fed.Reg. 9286 (February 15, 1977))). As we will show, however, the issue should not be resolved judicially at this time. Moreover, the lower court's decision is fully supported by the language and purposes of the federal Act, by the F.D.A.'s regulations and interpretations of the Act, and by the decisions of every court that has considered the question.

A. Under The Primary Jurisdiction Doctrine, This Court Should Not Assume Jurisdiction To Consider The Preemption Issue Raised By Appellant Because That Issue, Pursuant To Congress' Directive, Is Currently Pending Before The Food And Drug Administration.

1. Pursuant To The Procedure Established In The Medical Device Amendments Of 1976, The F.D.A. Has Preliminarily Ruled That Section 26463(m) Is Either Not Preempted Or Is Exempt From Preemption.

The Medical Device Amendments of 1976 were enacted to provide the Food and Drug Administration with broader authority to regulate the safety and effectiveness of medical devices. While Congress envisioned that federal regulation would be preeminent in the area, it did not intend federal law to preempt all state regulation of medical devices. Instead, in section 521 of the Act (21 U.S.C. § 360K), it carefully established standards for when state regulation of medical devices should be preempted. Under section 521, state laws were only to be preempted if all the conditions set forth in section 521(a) of the Act were met. Section 521(a) reads:

> "Except as provided in subsection (b) of this section, no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, **and**
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Even where it is shown that all these prerequisites have been met, however, preemption is not always required. Section 521(b) of the Act (21 U.S.C. § 360K(b)) allows the F.D.A. to exempt from preemption state laws that are more stringent than the federal requirements; it reads:

> "Upon application of a state or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a

requirement of such state or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

In response to the federal statute, the California Department of Health submitted an application requesting, *inter alia,* that to the extent California's Sherman Act provisions applicable to medical devices might be preempted, that they be exempted from preemption because they were more stringent than the federal requirements.

In response to that application, on February 15, 1977, the F.D.A. issued a proposed regulation (Proposed 21 C.F.R. § 808.55) granting California's application for exemption (42 Fed.Reg. 9186).[8] The proposed regulation reads, in relevant part:

"(a) The following California medical device requirements are enforceable notwithstanding section 521 of the Federal Food, Drug and Cosmetic Act, either because they are not preempted by section 521(a) or because the Commissioner of Food and Drugs has

[8]In the proposed regulation, the F.D.A. found that only one California statute (Business and Professions Code § 2541.3, dealing with opthalmic devices) had been preempted by the federal Act. 42 Fed. Reg. 9189.

granted an exemption from preemption pursuant to section 521(b) of the act:

"(1) Sherman Food, Drug, and Cosmetic Law (Division 21, Health and Safety Code)."

Since Division 21 of the Sherman Food, Drug, and Cosmetic Law includes Health and Safety Code section 26463(m), the F.D.A. clearly did not intend to preempt the statute at issue here.[9]

On the same day, February 15, 1977, the F.D.A. published final regulations (effective August 15, 1977) setting out requirements for labeling hearing aids; the purpose and scope of these regulations specifically did not include regulation of hearing aid advertising:

"The Food and Drug Administration (FDA) is establishing uniform professional and patient *labeling* requirements and conditions for sale of hearing aid devices. The regulations prescribe the *types of information that must be included in the labeling* to provide hearing professionals and patients with adequate directions for the safe and effective use of a hearing aid; specify the technical performance data that must be included in the *labeling* to ensure that hearing health professionals have adequate information to select, fit, and repair a hearing aid for a patient; and restrict the sale of a hearing aid to those patients who have undergone medical evaluation within the past 6 months, but with a provision that fully informed adult patients (18 years of age or older) may waive the medical evaluation because of personal or religious beliefs." (42 Fed.Reg. 9286) (Emphasis added).

[9]Proposed section 808.55(a)(1) is still pending before the F.D.A.

Indeed, the F.D.A. noted that regulation of hearing aid sales practices, including advertising, were not within the scope of its authority but would be left to the Federal Trade Commission (hereinafter "F.T.C."). 42 Fed.Reg. at 9286.

On May 2, 1978, the F.D.A. published final regulations establishing detailed standards and procedures for considering applications for exemptions from the federal Act. 21 C.F.R. §§ 808.1-.35. 43 Fed.Reg. 18661 *et seq.* Those regulations established that under section 521(a) of the Act, state laws would be preempted only when the F.D.A. had established "specific counterpart regulations" applicable to the device. 21 C.F.R. § 808.1(d).[10]

Finally, and of critical importance to the instant case, on July 26, 1978, the F.D.A. published proposed regulations granting the applications for exemptions of state hearing aid requirements from preemption submitted by several states, including California. Under these proposed regulations, the F.D.A. has specifically ruled that California Health and Safety Code section 26463(m) is *not* preempted by federal law; the F.D.A. states:

> "The Commissioner is also proposing to exempt from preemption California's Health and Safety Code, section 26463(m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521(a) of the act." (43 Fed.Reg. 33182).

[10]Section 808.1(d) reads, in relevant part:

"(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements."

Thus, the precise question appellant raises is currently being considered in the forum Congress explicitly intended it be determined—the Food and Drug Administration. As we will explain in the next section, given the pendency of the F.D.A.'s regulations, a determination of the preemption issue by this Court at this time would run directly contrary to this Court's "primary jurisdiction" doctrine.

2. The F.D.A. Has Primary Jurisdiction Over The Preemption Issue Raised By Appellant, And Resolution Of That Issue By This Court Is Premature And Unnecessary.

The primary jurisdiction doctrine recognizes that where, as here, Congress has looked to the agency with expertise in the field to determine the scope or application of federal law, deference to the administrative agency is appropriate. In *Far East Conference v. U.S.*, 342 U.S. 570, 574 (1952), this Court said:

> "The Court thus applied a principle, now firmly established, that in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion,

agencies created by Congress for regulating the subject matter should not be passed over."[11]

In the instant case, the F.D.A. has great expertise in the regulation of medical devices and public health matters generally. Since the preemption issue raised by appellant is currently being considered by the F.D.A., a judicial determination prior to an administrative determination would be a particularly inefficient use of judicial resources.

Furthermore, there would be no prejudice to appellant from dismissal of its appeal in light of the F.D.A. proceedings. Should the F.D.A. reverse its proposed determination and decide that Health and Safety Code § 26463(m) is preempted, then, under the California Superior Court's inherent power to vacate prohibitory injunctions upon a showing of a change in the law, appellant can have the superior court's injunction dissolved.[12]

On the other hand, should the F.D.A. finalize its proposed regulation and decide that the statute is not preempted or is exempt from preemption, then appellant may seek judicial review of that order in a separate action. 5 U.S.C. § 702.

Thus, given the F.D.A.'s primary jurisdiction, and the remedies available to appellant from that decision, no substantial preemption question is properly before this Court at this time. *See, Far East Conference v. U.S., supra,* 342 U.S. at 495-496; *see also, U.S. v. Michigan National Corp.,* 419 U.S. 1 (1974) (per curiam).

[11]On the doctrine of primary jurisdiction generally, see 3, K. Davis, *Administrative Law Treatise,* Ch. 19.

[12]*Sontag Chain Stores Co. v. Superior Court,* 18 Cal.2d 92, 94-95, 113 P.2d 689 (1941); *cf., New Jersey Guild of Hearing Aid Dispensers v. Long,* 75 N.J. 544, 384 A.2d 795, 814 (1978).

B. Section 26463(m) Complements The Purposes Of The Federal Act And Regulations, And Thus Under Section 521 Of The Act Is Either Not Preempted Or Is Exempt From Preemption.

Although appellees respectfully submit that determination of the preemption issue raised by appellant is unnecessary, it is also clear that, on the merits, no substantial preemption question is presented.

Questions of preemption are basically questions of federalism. *Jones v. Rath Packing Co.,* 430 U.S. 519, 525 (1977). Thus, the extent of the state's prior involvement in the regulated field is a critical factor. If the area is one traditionally regulated by the states, then there is a presumption against federal preemption which only can be overcome by showing a "clear and manifest" intent by Congress to preempt state regulation. *Ibid; see also, New Jersey Guild of Hearing Aid Dispensers v. Long,* 75 N.J. 544, 384 A.2d 795, 808 (1978).

California has long regulated medical drug and device advertising under its plenary power to protect the public welfare.[13] Appellant, however, has entirely failed to show that the presumption against preemption that results from California's historical involvement in regulating medical device advertising has been overcome by a "clear and manifest" congressional intent to preempt California law. The reason for this failure is apparent—no such intent exists. An examination of the federal scheme reveals that the federal Act and regulations are concerned with an entirely dif-

[13]*See, e.g., Neslen v. Board of Health,* 70 Cal.App.2d 202, 160 P.2d 862 (1945); *California Cancer Quack Laws: The Best Is None Too Good,* 40 So.Cal. L.Rev. 384 (1967).

ferent aspect of the hearing aid industry than is addressed by section 26463(m), and thus there was no intent by Congress either explicitly or implicitly to preempt California's Sherman Act provisions for the regulation of hearing aid advertising.

1. There Is No Counterpart Federal Regulation To Section 26463(m) Because The Federal Act And Regulations Are Primarily Concerned With The Safety And Effectiveness Of Hearing Aids, Not Sales Practices Like Advertising.

California's regulation of hearing aid advertising is not explicitly preempted under section 521(a) of the Federal Food and Drug Act because section 26463(m) is not "different from, or in addition to any requirement" under the Act or F.D.A. regulations. 21 U.S.C. § 360K(a)(1). As the court of appeal found, the federal "requirements" deal only tangentially with the subject of advertising. (J.S. at 34). As noted previously, the primary concern of the F.D.A.'s regulations is labeling, not advertising;[14] in fact, the F.D.A. regulations totally ignore the field of hearing aid advertising. Thus, in the absence of "any specific counterpart regulations" (21 C.F.R. § 808.1(d)), there is no federal requirement which the statute can be "different from, or in addition to".[15]

[14]The critical difference between labeling and advertising is that while the former is objective and informational, the latter involves an intent to induce the purchase of the device. Compare California Health and Safety Code sections 26016 (defining "label") and 26002 ("advertisement").

[15]*See, Ray v. Atlantic Richfield Co.,* U.S. , 98 S.Ct. 988, 1001 (1978) (although federal agency could have enacted regulations preempting state law, in absence of any specific regulations on subject, state law not preempted.)

The court below is not alone in recognizing the difference between regulating hearing aids as devices and regulating hearing aid sales practices. In *New Jersey Guild of Hearing Aid Dispensers v. Long,* 75 N.J. 544, 384 A.2d 795 (1978), the Supreme Court of New Jersey held that New Jersey's laws regulating hearing aid sales practices were not preempted by the federal Act and F.D.A. regulations. The essence of the court's holding was that hearing aid sales practices were not within the scope of section 521(a) of the federal Act:

> "Key aspects of dispensing sales practices covered by the [state] regulations are left largely unregulated by the F.D.A. hearing aid regulations, which relate predominantly to requirements of labeling and conditions of sale." (384 A.2d at 811).

The court thus held that New Jersey regulations prohibiting door-to-door canvassing, banning misleading professional titles and regulating other sales practices were not preempted by federal law.

In *New York State Hearing Aid Society v. New York,* Civ. No. 76-C-1565 (E.D. N.Y. March 10, 1978),[16] the court held that New York's statutes regulating the sales practices of hearing aid dealers were not preempted by the F.D.A. regulations:

> *"The federal regulations are aimed at the safety and effectiveness of devices, not the manner in which they are sold.* Thus, while the state statute may not, absent exemptions, regulate guarantees and receipts in the face of superceding federal regulations, neither the supremacy clause of the Constitution nor Section 360k

[16]A copy of the district court's Memorandum and Order is appended hereto as Exhibit 2.

> of Title 21 prohibits the state from controlling who sells a hearing aid device *or the manner in which it is sold.*" (Ex. 2, p. 6) (Emphasis added).

The court went on to specify that New York laws prohibiting door-to-door canvassing and false, misleading, deceptive, or untruthful advertising were specifically *not* within the realm of the federal regulations, and therefore, not preempted. (Ex. 2, pp. 6-7).

Both the New Jersey and New York courts made essentially the same finding as the court of appeal in this case—that the federal regulations are concerned with the safety and effectiveness of the device itself and with the labeling that goes with the device, not with the sales practices and advertisements used to promote the device. Since that aspect of regulation of the hearing aid industry is left to the states, it is not preempted by federal law.

Thus, as the court of appeal correctly found, Health and Safety Code section 26463(m) is not a "requirement" within the meaning of section 521(a). It does not require hearing aid advertisers to do or say anything. Its only effect is to prohibit representations which have not been medically verified by the State Department of Health. Unlike the labeling requirements in *Jones v. Rath Packing Co., supra,* referred to by appellant, it does not "require" a different kind of information than the federal agency, and thus does not create an inevitable conflict. Furthermore, any information the F.D.A. might require would be allowed under state law pursuant to Health and Safety Code section 26465.

Appellant also refers to 21 U.S.C. section 352(r), which it claims "reveals a clear intent to control the content of

'all advertisements' of a restricted device". (J.S. at 10). However, this position is thoroughly negated by both the language of the statute itself and the F.D.A.'s interpretations of its meaning. Section 352(r) reads in relevant part:

> "A drug or device shall be deemed to be misbranded . . .
> **(r) In the case of any restricted device distributed or offered for sale in any state, unless the manufacturer, packer or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type of at least half as large as that used for any trade or grant name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications. . .**"

The statute, in requiring that any advertisements contain a "brief statement of the intended use of the device", does not mandate or encourage hearing aid advertising, as appellant claims. It only requires that *if* medical devices are advertised, they must contain the required warnings.

Moreover, it certainly does not require "performance claim" or "product promotion" advertising like the appellant's; it only requires an objective statement of the uses of the device (*i.e.,* "hearing aids are used to amplify sound").

The F.D.A. has interpreted section 352(r) as leaving the field of hearing aid sales practices, including advertising, to the Federal Trade Commission. Prior to the F.D.A.'s

regulations, the F.T.C. had proposed to regulate hearing aid sales practices. Its regulations would require warnings and prohibit certain representations in hearing aid advertising. 40 Fed.Reg. 26646 (June 24, 1975); the F.T.C. regulations expressly would *not* preempt state laws which provide consumers greater rights. 40 Fed.Reg. 26651.

These F.T.C. advertising regulations "complement rather than conflict" with the F.D.A.'s labeling regulations, in the view of the F.D.A. 42 Fed.Reg. at 9286. Noting that the F.T.C.'s regulations are "particularly within the F.T.C. statutory mandate and expertise", the F.D.A. expressly stated its intent to leave federal regulation of the field of hearing aid advertising to the F.T.C. *Ibid.*[17]

The F.D.A.'s opinion on this matter is entitled to great weight, especially since it involves the construction of a new statute by the agency Congress has chosen to implement it. *Udall v. Tallman,* 380 U.S. 1, 16 (1965); *see,* cases cited in *New Jersey Guild of Hearing Aid Dispensers v. Long, supra,* 384 A.2d at 810.

2. Appellant Can Comply With Both Section 26463(m) And Federal Law, And Thus Section 26463(m) Is Not "Different From, Or In Addition To" Any Federal Requirement Pertaining To Hearing Aids.

Even assuming that there are federal "requirements" relating to hearing aid advertisements, they clearly are not "different from, or in addition to" California's Sherman

[17]Indeed, this policy is expressed in the F.D.A.'s July 26 proposed ruling that section 26463(m) is not preempted by federal law; the F.D.A. said "if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521 (a) of the act." 43 Fed.Reg. at 33182.

Act prohibition. Under *Jones v. Roth Packing Co., supra,* a state law is not "different from" a federal requirement if it is possible to comply with the state requirement without violating any federal requirements. This Court said in *Jones:*

> "Since it would be possible to comply with the state law without triggering federal enforcement action we conclude that the state requirement is not inconsistent with federal law." (430 U.S. at 540).[18]

In the instant case, the information which must be included under 21 U.S.C. section 352(r) if hearing aids are advertised is not inconsistent with section 26463(m). A statement of the "intended uses of the device and relevant warnings, precautions, side effects, and contra-indications" does not require appellant to represent that hearing aids will have an effect on "diseases or disorders of the ear"; it can be easily complied with by simply saying that hearing aids "amplify sound".

Moreover, the main thrust of the F.D.A. regulations is to encourage persons with hearing disorders to have a *medical* evaluation, not to buy a hearing aid like they would buy a freezer or a vacuum cleaner. In explaining its medical evaluation requirement, the F.D.A. said:

> "[T]he medical evaluation requirement is based principally on the recognition that an unnecessary or partially effective hearing aid may be substituted for primary medical or surgical treatment, thus depriving the hearing impaired patient of the benefit of appropriate medical diagnosis and care and resulting in a detriment to health. In addition to delaying proper medical

[18]*See also, New Jersey Guild of Hearing Aid Dispensers v. Long, supra.*

> diagnosis and possibly reducing the efficacy of corrective treatment, the purchase of a hearing aid which cannot attain its intended effect undoubtedly involves a high and unnecessary cost to the consumer. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased." (41 Fed.Reg. 16760).

This policy is entirely complementary to, not "different from", that expressed in section 26463(m). It is totally *inconsistent* with the tone and purpose of appellant's advertising campaign.

Indeed, the F.D.A. has recognized the problems caused by hearing aid advertisements in the past. Thus, it requires a specific disclaimer as to the effects of hearing aids in its labeling requirements. The User Informational Brochure packaged with each aid must contain "a statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions." 21 C.F.R. §801.420 (c) (1) (viii). The F.D.A.'s rationale for this labeling requirement is totally consistent with the California statute's purposes with respect to advertising:

> "The Commissioner believes that the statement in the proposal that hearing aids do not restore normal hearing and do not prevent or improve hearing loss is necessary to protect prospective hearing aid users from misleading claims about the benefits to be expected from a hearing aid and, accordingly, is retaining the requirement that this statement appear in the User Instructional Brochure. Some promotional material for hearing aids, in the past, has been worded to imply that the hearing aid would restore normal hearing or would prevent or improve the organic conditions causing hearing loss." (42 Fed.Reg. at 9291).

3. Even If Section 26463(m) Meets The Standards Set Out In Section 521(a) Of The Act, It Is Exempt From Preemption Under Section 521(b) Because It Is More Stringent Than Federal Law.

Even assuming *arguendo* that section 26463 meets the prerequisites of section 521(a) of the Act, it is clearly more stringent than the federal requirements and thus exempt from preemption under section 521(b). Indeed, as we have noted (*ante*, pp. 16-17), the F.D.A. has already proposed to exempt section 26463(m) from preemption, on the grounds that "to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the F.D.A. requirements". 43 Fed.Reg. at 33182.

4. Given The Statutory Mechanism Congress Has Created For Determining Preemption, The Implicit Preemption Doctrine Is Inapplicable To The Instant Case.

Appellant argues that even if the federal law does not explicitly preempt the entire field of hearing aid advertising, section 26463(m) is still contrary to federal law and thus invalid under the Supremacy Clause. However, in light of the detailed standards and procedures established by Congress to determine preemption, there is no place for the application of the implicit preemption doctrine in this case.

In the field of medical device regulation, Congress has provided that state regulatory law is not to be considered as an obstacle to the purposes of federal law *unless* it is determined to be so by the Food and Drug Administration.

In these circumstances, appellees submit that it would be inappropriate to evaluate, independent of the preemption procedure established by Congress, whether the state statute conflicts with the federal Act. By establishing such a preemption process, Congress anticipated that federal regulation would not be exclusive, and a determination by the courts based on their reading of the Act might well conflict with the degree of federal preemption that Congress envisioned—*i.e.*, what the F.D.A. determines should be regulated by the states under sections 521(a) and (b). *See, New Jersey Guild of Hearing Aid Dispensers v. Long, supra,* 384 A.2d at 813.

None of the cases cited by appellant (J.S. at 16) involve a similar delegation of the responsibility for determining preemption to the federal agency enforcing federal law. Thus, *Jones v. Rath, supra,* and other similar cases appellant relies on are wholly inapposite here, where Congress has entrusted responsibility for determining preemption to the F.D.A., not to the courts.

Moreover, Congress' creation of a mechanism to exempt more stringent state laws from preemption "is persuasive evidence of a Congressional intent to permit supplementary state regulation in the same field". *New Jersey Guild of Hearing Aid Dispensers v. Long, supra,* 384 A.2d at 813. Thus, as the New Jersey Supreme Court cogently stated:

> "[I]n view of the establishment of this innovative exemption mechanism, it seems accurate to say that there is nothing 'implicitly contained in [the FDCA's] structure and purpose,' *Jones, supra,* 430 U.S. at 525 . . . from which an unambiguous Congressional intent to preempt concurrent state regulation is reasonably inferable." (*Id.* at 814).

Therefore, as the New Jersey Supreme Court found,[19] the implicit preemption doctrine is inapplicable to the Medical Device Amendments of 1976, and to the case *sub judice.*

5. Health and Safety Code Section 26463(m) Does Not Conflict With Federal Policy, But Rather Complements It By Buttressing The Medical Evaluation Requirement And Requiring Medical Devices To Be Safe For Self-Medication Before They Are Advertised To The Public.

Appellant's conflict argument also must fail because California's section 26463(m) is entirely consistent with the policies expressed by Congress and the F.D.A. Under the implicit preemption doctrine, preemption only results where compliance with both federal and state regulations is "a physical impossibility"[20] or where the state law "stands as an obstacle to the full purposes and objectives of Congress."[21] As we have shown, however, nothing in the California statutory scheme requires hearing aid manufacturers to violate federal law.

Moreover, the state and federal provisions fully complement each other, to the public's benefit. California's law is designed to discourage self-help treatment of hear-

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[19] 384 A.2d at 814.

[20] *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143 (1963).

[21] *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941).

ing disorders and diseases, and to encourage medical evaluation. It is also designed to prevent the public from being exploited by medical device manufacturers hawking expensive devices with alluring promises of relief from medical conditions. (*See,* section 26465). These are precisely the same purposes sought to be served by the F.D.A. regulations. (*See* 41 Fed.Reg. at 16760, quoted *ante* at pp. 25-26; 42 Fed.Reg. at 9288.)[22]

Thus, the preemption issue raised by appellant presents no substantial federal question requiring this Court to assume jurisdiction of this case.

II. The Court Below Was Correct In Holding That Health And Safety Code Section 26463(m) And The Injunction Issued Pursuant To It Do Not Infringe Upon Appellant's Constitutional Right To Free Speech.

A. A Ruling On The Constitutional Issue Raised By Appellant Is Inappropriate And Unnecessary.

1. The Constitutional Issue Raised Here Was Not Decided By The Court Below Because The Court Correctly Found That Appellant's Advertisments Were Misleading And Thus Not Constitutionally Protected.

Appellant argues that section 26463(m) is unconstitutional because it prohibits the dissemination of truthful

[22]It is noteworthy that the F.D.A.'s endorsement of "ethical selling practices" by hearing aid dispensers cited by appellant (J.S. at 17) is not an endorsement of hearing aid advertising. Instead, it refers to "trial-rental or purchase option" plans that allow the customer to experiment with different hearing aids *after* having had a medical evaluation.

representations. (J.S. at 21). However, the court of appeal made a specific factual determination that appellant's advertisements were *not* truthful; instead, they were misleading and unlawful because they convey the false impression that hearing aids will have a curative or therapeutic effect on hearing loss. (J.S. at 31-32). As such, the court properly held that Dahlberg's advertisements fall outside the scope of the First Amendment. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976) (hereafter the *"Virginia"* case); *Bates v. State Bar of Arizona,* 433 U.S. 350, 383 (1977) (hereafter the *"Bates"* case).

Appellant virtually admits that the advertisements it ran in magazines of national circulation were misleading; it nowhere contests the finding of the court below. Indeed, it concedes that hearing aids are "not 'curative or therapeutic devices' " (J.S. at 21), although, as the court below correctly found, that is the impression conveyed by the advertisements.[23] As such, the court below correctly declined to rule on the constitutional issue raised here by appellant, and that issue is not properly before this Court. Rule 16(b), Rules of the Supreme Court of the United States.

2. Appellant Cannot Challenge The Statute's Effect On Non-misleading Advertising Because The "Overbreadth" Doctrine Is Not Applicable To Claims Of Infringement On The Right To Free Speech.

Appellant argues that regardless of whether its advertisements are truthful, it should be permitted to challenge

[23]See Exhibit 1.

the statute's applicability to truthful advertisements under the "overbreadth" doctrine. But as Justice Blackmun instructed in *Bates, supra,* the overbreadth doctrine has little relevance in commercial speech cases:

> ". . . the justification for the application of overbreadth analysis applies weakly, if at all, in the ordinary commercial context. As was acknowledged in *Virginia Pharmacy Board v. Virginia Consumer Council*, 425 U.S. at 771 n.24, there are 'commonsense differences' between commercial speech and other varieties. See also *id.*, at 775-781 . . . . Since advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation." (433 U.S. at 380-381).

Appellant, however, asserts that there are "compelling reasons" why this Court should ignore its own prior ruling in this case. (J.S. at 22). The reasons it offers, however, are hardly compelling; in fact, they are simply a rehash of the same arguments it makes on the merits of its constitutional claim,[24] not reasons for applying the overbreadth doctrine to commercial free speech cases.

The truth of the matter is that appellant has never presented a "truthful" advertisement to this Court, to the courts below, or to the California Department of Health. If appellant has real objections to California's regulation of truthful advertising, it is not unreasonable to require it to demonstrate the kinds of truthful advertisements it

[24]For example, appellant argues that the state statute frustrates the purposes of the federal Food and Drug Act. Even if true, the relevance of that point to this Court's overbreadth doctrine is tenuous at best. Moreover, as we have shown (*supra*, pp. 29-30), and as the F.D.A. has indicated, section 26463(m) fully complements the federal Act and regulations.

wishes to circulate. As Justice Blackmun noted in *Bates,* there are "common sense differences" between commercial speech and other types of protected speech.[25] Unlike other types of protected speech, a requirement that appellant demonstrates its own commercial speech is protected imposes no undue burden on it; on the other hand, the grave dangers to public health that have resulted from appellant's prior advertising practices demand no less.

3. The First Amendment Issue Was Not Timely Raised.

Resolution of the constitutional issue raised by appellant also is not appropriate because it is well established that this Court will not pass on the constitutionality of a state statute unless a party has consistently presented its claim throughout the proceedings below. Rule 16(b); *Cohen v. California,* 408 U.S. 15 (1971); *Street v. New York,* 394 U.S. 576 (1969).

Appellant did not contest the constitutionality of section 26463 in the trial court, but first raised it on appeal to the state District Court of Appeal.[26] By failing to assert its constitutional claim in the trial court, appellant is not entitled to review by this Court of that claim.

[25]*Bates, supra,* 433 U.S. at 381.

[26]Appellant contends that it is excused from raising the First Amendment issue in the trial court because this Court's decision in *Virginia State Bd. of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) "had not yet been announced". (J.S. at 7). No authority is cited to support its contention that a subsequent decision excuses its failure to raise the issue in the trial court. Moreover, contrary to appellant's assertion, the "commercial free speech" issue had been raised and decided before three judge courts in both the *Virginia case* (373 F.Supp. 683 (E.D. Va. 1974)) and, in California, in *Terry v. Calif. State Bd. of Pharmacy,* 395

B. Section 26463 Is A Valid Exercise Of The State's Authority To Protect The Public Health, Safety And Welfare, And Therefore Is Constitutional.

1. The Purposes Of Section 26463(m) Are To Protect The Public Health, Safety, And Welfare, And Thus Fall Within The State's Traditional Police Powers.

Assuming *arguendo* that appellant is entitled to raise the issue, it is clear that California Health and Safety Code section 26463 is constitutional.

As the trial court noted, section 26463 was adopted in order to implement two important legislative policies:

(1) To encourage the general public to seek qualified medical care for the conditions listed in section 26463; and

(2) To prevent the commercial exploitation of the general public by clever advertisements of drugs or devices, devices that may be useful in the proper circumstances and manner, but whose use the general public is unable to diagnose for itself. (J.S. at 41).

Given these clear and undisputable public purposes, the constitutionality of Health and Safety Code section 26463 and its predecessor statutes has been repeatedly upheld by the California courts as within the state's

F.Supp. 94 (N.D. Cal. 1975), *sum. aff'd.* 426 U.S. 913 (1976), prior to the time plaintiffs filed their motion for summary judgment in this case. Indeed, this Court noted that *prior* to the hearing in the trial court, "the notion of unprotected 'commercial speech' all but passed from the scene" (*Virginia State Bd. of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc., supra,* 425 U.S. at 759) as a result of this Court's landmark decision in *Bigelow v. Virginia,* 421 U.S. 809 (1975). Thus, appellant's claim that it believed commercial speech to be unprotected cannot excuse its failure to timely raise the issue.

police power. *People v. Ryan,* 101 Cal.App.2d 927, 226 P.2d 376 (1951); *People v. Galway,* 120 Cal.App.2d 45, 260 P.2d 212 (1953); *People v. Hohensee,* 251 Cal.App.2d 193, 59 Cal.Rptr. 234 (1967).

This Court has likewise recognized the important state interests in regulating advertising in the public health area. In *Semler v. Oregon State Bd. of Dental Examiners,* 294 U.S. 608 (1935), this Court upheld a statute restricting advertising by dentists; it stated:

> "The legislature was not dealing with traders in commodities, but with the vital interest of public health, and with a profession treating bodily ills and demanding different standards of conduct from those which are traditional in the competition of the market place. The community is concerned with the maintenance of professional standards which will insure not only competency in individual practitioners, but protection against those who would prey upon a public peculiarly susceptible to imposition through alluring promises of physical relief." (294 U.S. at 612).

This rationale is directly applicable to sellers of medical devices like hearing aids; the protection from "alluring promises of physical relief" afforded by section 26463 is similarly necessary to protect the health of California's residents.

2. Section 26463's Prohibition of Performance Claim Advertisements Is Valid In Light Of The Recent "Commercial Speech" Cases.

Appellant cites this Court's recent decisions in the *Virginia* and *Bates* cases in support of its argument that section 26463 violates its First Amendment free speech

rights. However, both the *Virginia* and *Bates* cases dealt solely with price advertising, not performance claim advertising like the instant case. Although appellant attempts to minimize the importance of the distinction between price advertising and performance claim advertising (J.S. at 25), this Court has recognized that the distinction is critical.

In *Bates*, this Court held that Arizona's prohibition against advertisements of the prices of routine attorney services was unconstitutional. In so doing, however, this Court recognized that performance claim advertising (or advertising going to the quality of or need for goods and services) may properly be subjected to regulation to protect the public interest, without running afoul of the First Amendment:

> "[B]ecause the public lacks the sophistication concerning legal services, misstatements that might be overlooked or deemed unimportant in other advertising may be found quite inappropriate in legal advertising. For example, advertising claims as to the quality of services —a matter we do not address today—are not susceptible to measurement or verification; accordingly, such claims may be so likely to be misleading as to warrant restriction." (433 U.S. at 383-384). (Footnote omitted).

As the trial court below noted, to allow unrestricted advertising of medical devices would pose serious threats to the public health by increasing the likelihood that physical ailments will be misdiagnosed and thus receive improper treatment—or undiagnosed and receive no treatment at all until it is too late. Thus, the dangers created by unrestricted performance claim advertising of medical devices like hearing aids are at least equal to the potential dangers of unregulated attorney advertising at issue in *Bates*.

The distinction between price and product promotion advertising was similarly articulated in *Terry v. California State Board of Pharmacy*, 395 F.Supp. 94 (N.D. Cal. 1975), *sum. aff'd.* 426 U.S. 913 (1976). In that case, a three-judge district court struck down as violative of the First Amendment a California statute prohibiting price advertising of prescription drugs. In so doing, the court stated that its decision was limited to price advertising, and that it would have reached a different result if the statute had dealt with product promotion or performance claim advertising:

> "It is undisputed that promotional product advertising is less vigorously protected than other forms of speech . . . 'Promoting the sale of a product is not ordinarily associated with any of the interests the First Amendment seeks to protect. As a rule, it does not affect the political process, does not contribute to the exchange of ideas, does not provide information on matters of public importance, and is not, except perhaps for the ad-men, a form of individual self-expression. It is rather a form of merchandising subject to limitation for public purposes like other business practices.'" (395 F.Supp. at 101-102, *quoting Banzhaf v. F.C.C.*, 405 F.2d 1082, 1101-1102 (D.C. Cir. 1968) *cert. denied* 396 U.S. 842 (1969)).

The court then contrasted price advertising of prescription drugs with product promotion advertising:

> "Prescription drugs may only be purchased when medically necessary. The consumer does not freely choose to buy the product; he is directed to do so by his physician. The information sought here will make it more likely that plaintiffs will be able to purchase these health essential items. The promotional advertising of cigarettes and submarine tours seeks to generate new

demand for goods by consumers who had expressed no previous interest in the products. By touting the virtues of the product, the advertising is intended to create a commercial transaction that would not otherwise occur. Insofar as the information sought here will create commercial transactions that would not otherwise occur, the health needs of the society are served, since a physician has already determined that the prescription drug, the product purchased, is medically necessary to the well-being of the consumer-patient. Further, the advertising sought here is limited to price and does not extend to promotional gimmicks extolling the product and generating artificial demand." (395 F.Supp. at 102).[27]

In the instant case, "the health needs of the society" are best protected by upholding section 26463—not by striking it down. The danger of allowing "promotional gimmicks" "extolling" hearing aids that create an "artificial demand" for them is very much present. Moreover, since there is no requirement that hearing aids only be purchased with a prescription, this danger is compounded because this "artificial demand" is often at the expense of proper medical treatment. Thus, the restrictions imposed by section 26463 are justified.

[27]The *Terry* rationale is in line with other cases which have held that promotional product advertising is entitled to significantly less protection than other forms of speech. *See, Banzhaf v. F.C.C.*, 405 F.2d 1082 (D.C. Cir. 1968), *cert. den.* 396 U.S. 842 (1969), affirming an FCC requirement that broadcasters who carry cigarette advertising must also provide a significant amount of time for presentation of anti-cigarette messages; *see also, Capital Broadcasting Co. v. Mitchell*, 333 F.Supp. 582 (D. D.C. 1971) (three judge court), *sum. aff'd.* 405 U.S. 1000 (1972), upholding the legislative ban of cigarette advertising in the electronic media.

3. The Significant And Compelling Public Policy Considerations Behind Section 26463 Justify Its Advertising Restrictions.

In balancing the State of California's interests against appellant's, it is clear that whatever First Amendment interests appellant may have at stake here are more than outweighed by the compelling public policy considerations behind section 26463.

In the present case, the appellant's interest in freedom of expression is relatively limited for several reasons. First, the restricted speech involves performance claim advertising of medical devices which, unlike *Virginia* and *Terry*, is not strictly informational; instead, it is subjective, self-serving, and beyond the capacity of the public to evaluate for itself. As such, it is "so likely to be misleading as to warrant restriction". *Bates, supra,* 433 U.S. at 383-384.[28]

Second, the appellant's sole interest as a manufacturer and advertiser is pecuniary.[29]

Third, and most important, given the underlying purposes of section 26463(m), the appellant's interests do not coincide with those of the general public but, in fact, conflict with the public interest. Unlike the *Virginia* case, where this Court found that the suppression of price advertising "hits the hardest [at] the poor, the sick, and particularly the aged" (425 U.S. at 763), in the instant case, it is this same group who is most often victimized by alluring promises of relief from hearing aid advertisers. (C.T. 303).

[28]*See also, Terry, supra,* 395 F.Supp. at 101.

[29]To the extent appellant may be interested in upgrading the level of knowledge about hearing aids, it may make performance claims about them in trade and medical journals despite section 26463(m). California Health & Saf. Code § 26464.

In contrast to the appellant's interests, the State's interests in enforcing section 26463(m) are compelling. Performance-type advertising for most drugs and devices must be regulated both because it may be dangerous, and because so many people are susceptible to manipulative and misleading advertisements inducing them to purchase useless devices.[30]

The findings by the United States Department of Health, Education and Welfare set out in *A Report of Hearing Aid Health Care* (C.T. 125-194, discussed *ante*, at p. 7) noted that approximately 70 percent of the persons who buy hearing aids go to a dealer first rather than to a physician. This can only be the result of the extensive advertising practiced in the hearing aid industry. Indeed, in this case, Dahlberg's advertisements produced almost 12,000 responses from California residents to its ads in a little over one year. (C.T. 213). Each of these persons then received a call or visit from a hearing aid dealer, rather than medical treatment. The tragic result of this unregulated advertising, as the HEW report noted, is that many persons with remedial ear disease go undiagnosed, trying one hearing aid after another, until they reach the point where the disease is no longer medically remediable. (C.T. 142). Moreover, the HEW report noted that in 40 percent of the cases studied in New York City and Baltimore, dealers recommended the purchase of hearing aids for persons when audiological centers had determined that the patient could not be helped by a hearing aid. (C.T. 133).

[30]*See, California Cancer Quack Laws: The Best Is None Too Good*, 40 So. Cal.L.Rev. 384 (1967).

The interests of the State of California and the lay public in preventing these abuses is clearly served by Health and Safety Code section 26463(m), and more than justify the limited restrictions placed on the appellant in this case.

C. The Advertising Prohibitions Of Section 26463 Are Not Overbroad Since They Utilize The Narrowest Approach Possible In Effectuating A Legitimate And Compelling Public Policy.

Appellant argues that section 26463 is unconstitutional because it prohibits truthful as well as false and misleading representations, and is therefore overbroad under the First Amendment. Assuming *arguendo* that it has standing to raise this argument, appellant's argument is without merit for several reasons.

First, as we have shown, a restriction on advertising of non-certified medical drugs and devices, whether true or false, is necessary to carry out the purposes of section 26463 because of the irreparable nature of the dangers to the public the statute seeks to prevent.

Second, Health and Safety Code section 26465 provides clear and precise standards under which proper medical device advertising is allowed. It also provides for an administrative determination by the California Department of Health that truthful performance claim advertising will be allowed if the drug or device is determined to be "safe and effective" self-medication. If appellant's advertisements do not present a danger to the general public, then they will be approved and can be used.[31] Thus, section

[31]*Cf.* Health and Safety Code section 26464.

26463's prohibition on truthful advertising is only as broad as is necessary to carry out its purposes.[32]

Third, contrary to appellant's assertions, the wording of the injunction is not overly broad. The injunction simply tracks the language of section 26463(m). To require the injunction to go only to the advertisements before the court would allow appellant to freely circumvent the statute by using different, but similarly objectionable, advertisements. This Court has recognized that courts must have some latitude in making orders to prohibit such illegal activity:

> "We think it reasonable for the Commission to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future advertisements. As was said in *Federal Trade Commission v. Ruberoid Co.*, 343 U.S. 470, 473, '[T]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past.' Having been caught violating the Act, respondents 'must expect some fencing in'." (*Federal Trade Commission v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965)).

[32]Appellant argues that the protections afforded by section 26465 are inadequate because there is no guarantee that the Department of Health will allow truthful advertising under that section. However, this argument is purely speculative and hypothetical, since the appellant has never tried to obtain permission to advertise its hearing aids. It assumes, without any justification or basis, that the State of California will act in bad faith.

Moreover, California law provides adequate procedural protections for the appellant should the Department of Health act arbitrarily. As appellant notes, under California Government Code section 11427, appellant has the right to petition the Department of Health to promulgate a regulation allowing it to advertise hearing aids in compliance with section 26465. If the Department of Health, despite the mandatory language of section 26465, should refuse to consider Dahlberg's application for approval of its advertisements, Dahlberg can obtain a writ of mandate requiring the Department to act, pursuant to California Code of Civil Procedure section 1085. Should the Department deny the application, Dahlberg can seek judicial review of that decision pursuant either to Code of Civil Procedure sections 1085 or 1094.5. *See, e.g., Carmona v. Division of Industrial Safety*, 13 Cal.3d 303, 309, 118 Cal.Rptr. 473 (1975).

Finally, sections 26463 and 26465 do not constitute an invalid prior restraint of freedom of speech. Appellant wrongly claims that the statutes carry a heavy presumption against their constitutional validity in light of the *Virginia* case; as we have shown (*ante*, pp. 35-38), however, the statutes at issue clearly meet the constitutional standards set forth in the *Virginia* and *Bates* cases.

Furthermore, section 26465 sets out clear and specific standards for when advertisements should be approved. Thus, the danger of unreviewable, standardless prior restraints is not present here.

Lastly, as discussed previously, this Court held in *Bates* that the overbreadth doctrine was not justified in commercial speech cases because there are "'common sense differences' between commercial speech and other varieties," and because it was "not necessary to further its intended objective". (433 U.S. at 381). This reasoning is equally applicable to the issue of prior restraint. No case has yet held the prior restraint doctrine applicable to purely commercial speech, and there is no reason to do so here. The interests of the general public in obtaining proper medical treatment and avoiding inappropriate medical devices far outweighs whatever harm, if any, is caused appellant by the restrictions on its product promotion advertising im-

posed under California law. An application of the prior restraint doctrine in this case would be unwarranted.

Thus, this case presents no substantial question as to the constitutionality of California Health and Safety Code section 26463(m).

CONCLUSION

For the reasons stated herein, the appeal should be dismissed, or the judgment of the court below affirmed.

Respectfully submitted,

RICHARD M. PEARL
California Rural Legal Assistance
JAMES RUMBLE
Attorneys for Appellees
George Kievlan, et al.

(Exhibits Follow)

Exhibits

I'M NOT DEAF
OUR DAUGHTER'S GRADUATION...: I COULD HEAR BUT I WASN'T ABLE TO UNDERSTAND THE WORDS
NEXT DAY...AT A DAHLBERG HEARING AID DEALERS...
MRS. GOODWIN, THE AUDIOMETRIC EXAMINATION SHOWS YOUR HEARING IS IMPAIRED IN THE HIGH TONES - YOU'RE ABLE TO HEAR SOUNDS, BUT WHEN THERE'S A LOT OF BACKGROUND NOISE, YOU CAN'T ALWAYS UNDERSTAND WHAT'S SAID. IT'S A CLASSIC SYMPTOM OF NERVE IMPAIRMENT - SOMETIMES CALLED MILD NERVE DEAFNESS
YOU MEAN SHE'S GOING DEAF? ISN'T THERE SOMETHING THAT CAN BE DONE?
MOST LOSSES LIKE THIS COME ON GRADUALLY...OVER THE YEARS. YOU NEED HELP! AND THE MEDICAL EXPERTS GENERALLY AGREE THAT NO EFFECTIVE CURE HAS YET BEEN FOUND FOR THIS TYPE OF HEARING LOSS
YOU MEAN IT'S HOPELESS?
FEELS COMFORTABLE ENOUGH. BUT IT IS SO TINY. COULD IT POSSIBLY HELP?
LATER... AT THE PTA MEETING
FRED, THIS IS MARVELOUS. I CAN UNDERSTAND THE WORDS. IT'S THE FIRST TIME IN YEARS I'VE HEARD SO CLEARLY

EXHIBIT 1

PANIC STRUCK ME! COULD MY HEARING BE THAT MUCH WORSE? THE DOCTOR SAID I HAD A MILD NERVE DEAFNESS...BUT THERE WAS NO WAY HE COULD HELP ME.

AT HOME THAT NIGHT...
HERE'S THE MAIL, MOM
JUST BILLS...WHAT'S THIS? "MILD NERVE DEAFNESS... YOU HEAR, BUT DON'T ALWAYS UNDERSTAND". EXACTLY WHAT'S HAPPENING TO ME!

IT MIGHT HAVE BEEN DIFFERENT YEARS AGO, MRS. GOODWIN. BUT NOW, FORTUNATELY, MODERN SCIENCE HAS CREATED A TINY NEW ELECTRONIC DEVICE MADE TO HELP IN MOST CASES LIKE YOURS. DOESN'T EVEN LOOK LIKE ONE OF THOSE OLD-FASHIONED HEARING AIDS. YOU'LL NOTICE THERE ARE NO CORDS OR WIRES. AND YOU WEAR IT ENTIRELY IN YOUR EAR. IT'S CALLED MIRACLE-EAR!

GENTLEMEN:

Please tell me how I may be able to hear again more clearly in both ears without using hearing aids that have cords or tubes

JUST BILLS...WHAT'S THIS?

Your Name_____

Address_____

City_____

State_____ Zip Code_____

I Am Now Using (check one)

☐ Cord Type ☐ Behind the Ear Type

☐ Eyeglass Type ☐ No Aid

I understand that mailing this card places me under no obligation.

Tear off and mail today—no postage necessary

MAGAZINES ADVERTISING

I'M NOT DEAF!

Under normal conditions I hear well enough. But sometimes my ultra-miniature DAHLBERG MIRACLE-EAR® hearing aid is a blessing. I just put it in my ear and I hear more clearly.

It is so natural sounding — nothing above my ear or below my ear. Nothing behind or in front of my ear. No tubes, nor wires. No scratchy sounds.

It is especially designed for those who hear but do not always understand — a classic symptom of nerve impairment. If diagnosis* shows you have this type of loss, this modern hearing aid may give you the extra "lift" you need to live a full and active life.

Rush this coupon! Discover how you may be able to hear again in both ears without using hearing aids that have cords or tubes. NO OBLIGATION WHATEVER. * *Ask your doctor about Dahlberg Hearing Aids.*

MIRACLE-EAR®
P.O. Box 549, Dept. OG-373
Minneapolis, Minn. 55440

Please tell me how I may be able to hear again in both ears without using hearing aids that have cords or tubes.

NAME_____

ADDRESS_____

CITY_____ STATE_____ ZIP_____

IF YOUR DOCTOR SAYS YOU HAVE NERVE DEAFNESS . . .

THIS IS ALL YOU WEAR!

Miracle-Ear® may be all you need to hear clearly again. It fits entirely in your ear. Ideal for 7 out of 10 who can still hear but have trouble understanding words. Try it today. Come in, phone, or send the coupon.

Available only at our offices.

SHOWN TWICE THE ACTUAL SIZE.

Name _____

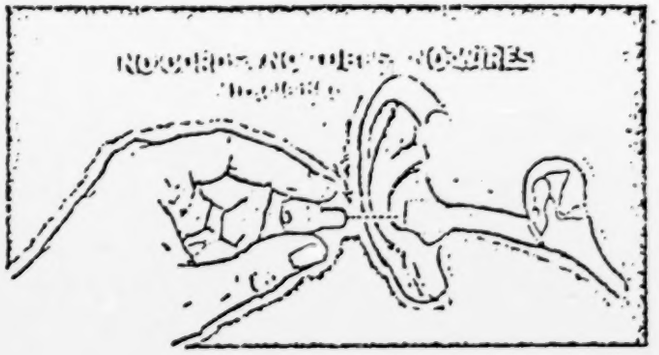
Address _____

City _____

State _____ Zip____

PROFESSIONAL HEARING AID CENTER
531 Hartnell 372-4293 Monterey

MILD NERVE DEAFNESS
The most common cause of hearing loss



Don't let another day go by before YOU realize how thrilling it could be to HEAR AGAIN more clearly! MIRACLE-EAR developed and patented by Dahlberg, may be EXACTLY what YOU have been hoping for!

PROFESSIONAL HEARING AID CENTER
531 Hartnell 372-4293 Monterey

Exhibit 2

United States District Court
Eastern District of New York

Docket No. 76 C 1565

New York State Hearing Aid Society Incorporated, et al.,
Plaintiffs,
— against —
State of New York, et al.,
Defendants.

MEMORANDUM AND ORDER

PRATT, J.:

Plaintiffs, individual hearing aid dealers and membership corporations composed of individual hearing aid dealers, have brought this action to declare unconstitutional and to enjoin enforcement of Chapter 274 of the Laws of 1976 of the State of New York, New York General Business Law §§ 780 *et seq.*, which established a regulatory scheme for the sale of hearing aids in New York State. The complaint is premised upon the supremacy clause in Article VI, § 2, of the Constitution, which, when coupled with the specific prohibition of 21 USC § 360k, plaintiffs urge, precludes the state from continuing or enforcing any regulation which conflicts with the national regulatory scheme for

the manufacture and sale of hearing aids embodied in 21 USC §§ 360 *et seq.*

In a memorandum and order dated December 3, 1976, the undersigned denied as premature a motion made by these plaintiffs to preliminarily enjoin enforcement of Chapter 274. By motion returnable March 10, 1977, plaintiffs both renewed their request for a preliminary injunction and sought summary judgment on their claims for declaratory and injunctive relief. Since the federal regulations were not yet in full force and effect, however, those applications were again denied as premature in a memorandum and order dated March 17, 1977. On August 25, 1977 the federal regulations took effect, and now before the court are plaintiffs' renewed motions for preliminary injunction and summary judgment, as well as defendants' crossmotion to dismiss pursuant to FRCP 12(b)(6).

I.

Preliminarily, defendants have challenged, and the court has examined, the standing of these plaintiffs to litigate the constitutionality of Chapter 274. Not only have the individual plaintiffs averred "actionable causal relationship" between the challenged regulations and their injury, *Warth v. Seldin,* 422 US 490, 507 (1975); *Village of Arlington Heights v. Metropolitan Housing Development Corp.,* 429 US 252 (1977), but the membership corporations also have averred the requisite factors enumerated in *Warth, supra* and *Hunt v. Washington State Apple Advertising Commission,* 97 SCt 2434 (1977). Moreover, defendants' assertions to the contrary notwithstanding, the issue is "ripe" for adjudication as will be more fully explained *infra.*

Section 360k of Title 21 of the United States Code provides, in part, that:

> [N]o State * * * may establish or continue in effect with respect to a device [such as a hearing aid] intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Defendants concede that part of the state regulatory scheme has been superseded by the federal regulations. In an affidavit filed September 16, 1977, plaintiffs' attorney wrote:

> 3. That on or about August 31, 1977 the Department of State of the State of New York, by Mario Cuomo, Secretary of State, issued a statement concerning the hearing aid statutes and the federal regulations. A copy of said statement is annexed hereto and marked as Exhibit A.
>
> 4. That your deponent respectfully submits that by said statement the defendant, the Secretary of State of the State of New York, has conceded that the federal regulations supersede the state statute in at least the manner set forth in the attached statement.

Not only does this statement fairly characterize the Secretary of State's letter of August 31, 1977, but, in an affidavit filed September 26, 1977, defendants' attorney stated: "I hereby stipulate to and acknowledge the accuracy of paragraph '3' and '4' of plaintiff's affidavit [filed September 16, 1977]." However, defendants contend that not

all of the state's requirements have been superseded, and that the remaining ones must be complied with. In his letter dated August 31, 1977 the Secretary of State went on to declare:

> The State requirement that a hearing aid dealer must be registered with this department in order to fit and sell hearing aids continues in effect. Other aspects of the State law and the rules of this department including but not limited to the provisions as to the 30-day guarantee, the receipt that must be provided, the required availability of repair and service, prohibitions against canvassing, et al. continue and must be complied with in all events.
>
> You are further advised that the federal food, drug and cosmetic act, the law under which the FDS regulations were adopted, permits the state to apply for exemptions for state requirements which are more stringent than those effected by the federal regulations. Requests for such exemptions are being made. Until you are advised otherwise, however, you must follow the federal regulations as indicated above.

Plaintiff's Aff. of September 16, 1977, Ex. A.

In its present form the controversy, simply stated, is that plaintiffs disagree with the Secretary of State when he says that the federal regulations did not supersede Chapter 274's provisions prohibiting door-to-door canvassing, regulating the availability of repairs and service, regulating the receipts and written documents to be given to hearing aid customers, the 30-day guarantee provisions, etc.

III.

Summary judgment shall be granted on their request for declaratory relief, insofar as New York's Secretary of State continues in the erroneous belief that New York **General** Business Law §§ 780 *et seq.* has not been superseded by the federal regulations governing the manufacture and production of a hearing aid device. The intent and effect of 21 USC §§ 360 *et seq.* and the regulations promulgated thereunder reserve to the federal government the power to control the manufacture, production, effectiveness, and standards relating to devices such as hearing aids. The supremacy clause of the Constitution and the clear prohibition of 21 USC § 360k, then, preclude the continuance and enforcement of those sections of New York General Business Law §§ 780 *et seq.* which also purport to regulate hearing aid devices.

Defendants correctly note that the State of New York may apply pursuant to 21 USC § 360k(b) and the regulations promulgated thereunder for an exemption from the federal regulations. Until such time that an exemption, if warranted, is granted, however, plaintiffs should not be threatened with enforcement of a state statute which, in respect to hearing aid devices themselves, is erroneously thought to be not superseded by the federal regulations.

Specifically, the court declares that the following provisions of the New York General Business Law have been superseded by the federal statutes and regulations:

> § 784(1), conceded by the Secretary of State to have been superseded, and relating to the written recommendations, testing, typing, waivers, etc. required before a hearing aid may be dispensed;

§ 784(3), relating to an itemized receipt;

§784(4), relating to the money-back guarantee and rebate provisions;

§784(9), relating to the disclaimer which must accompany a hearing aid device.

IV.

Insofar as New York General Business Law §§ 780 *et seq.* purports to regulate the vendors of a device rather than the device itself, such as the licensing of dealers, the state statute remains unaffected by 21 USC §§ 360 *et seq.* and the related regulations. The federal regulations are aimed at the safety and effectiveness of devices, not the manner in which they are sold. Thus, while the state statute may not, absent exemptions, regulate guarantees and receipts in the face of superseding federal regulations, neither the supremacy clause of the Constitution nor § 360k of Title 21 prohibits the state from controlling who sells a hearing aid device or the manner in which it is sold.

Specifically, the court declares that the following provisions of the New York General Business Law have not been superseded by the federal statutes and regulations:

§§ 780, 781, 782, and 783, which relate to the legislative intent, definitions, and registration requirements of Chapter 274;

§ 784(2) relating to door-to-door canvassing;

§§ 784(5)-(8), all of which relate to prohibitions against false, misleading, deceptive, or untruthful advertising;

§ 784(10) relating to sanctions;

§ 785 relating to the due process procedures provided should a certificate of registration be denied, suspended, or revoked;

§785-a relating to referrals and not for profit sales;

§ 786 relating to the powers of the Secretary of State to promulgate rules and regulations to effectuate the purposes of this article, of course, as modified by this decision; and

§ 787 relating to the separability of provisions.

Significantly, New York General Business Law § 787 specifically authorizes the selective declarations of invalidity on the specific provisions of Chapter 274 without impairing or invalidating any other sections or provisions of the chapter.

V.

The court is mindful that plaintiffs' complaint seeks a permanent injunction; indeed, plaintiffs have moved for a preliminary injunction. The court is persuaded, however, by defendants' affidavits and statements to the effect that the State of New York has no desire to continue enforcement of a state statute which has been superseded by federal regulations. In the face of an actual controversy between plaintiffs and defendants, a declaratory judgment is appropriate. The state has already suspended enforcement of New York General Business Law §§ 780 *et seq.* insofar as it conflicts with the federal regulations. Even without the state's voluntary compliance, plaintiffs have a complete defense to continued enforcement of the conflict-

ing provisions and, consequently, the court sees no value in entering an "unnecessary" injunction here; the declaratory judgment directed above will dispose of the action in its entirety.

Plaintiffs shall within 10 days submit on notice a proposed judgment for the court's signature.

SO ORDERED.

Dated: Westbury, New York

March 10, 1978.

GEORGE C. PRATT
George C. Pratt
U.S. District Judge